## ACNE TREATMENT- benzoyl peroxide gel Amazon.com Services LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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Solimo 229.001 229AC-AD

## **Active ingredients**

Benzoyl peroxide 10%

## **Purpose**

Acne medication

#### Use

for the treatment of acne

#### Warnings

For external use only

## Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

# When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with eyes, lips and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, buring, itching, peeling or posible swelling. Irritation may be reduced by using the product less frequently or in a lower concentration

# stop use and ask a doctor if

irritation becomes severe

#### Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer one to three times daily
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce daily application to once a day or every other day
- if going outside, apply sunscreen after using this product. If irritation or sensitivity develops stop use of both products and ask a doctor

#### inactive ingredients

carbomer, disodium EDTA, hydroxypropyl methylcellulose, laureth-4, sodium hydroxide, water

#### Claims

This acne medication contains maximum strength benzoyl peroxide. The micronized benzoyl peroxide formula goes to work immediately, releasing the medicine deep into the pore where pimples begin

#### **Adverse Reactions Section**

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29.001/229AC

# **Principal Display Panel**

Solimo

10% Benzoyl Peroxide

Acne Medication

MAXIMUM STRENGTH

Dermatologitsted For treatment of acne



NET WT 1 OZ (28 g)

Dermatologist tested For treatment of acne

10% Benzoyl Peroxide Acne Medication MAXIMUM STRENGTH

SOUMO



benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-229
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZOYL PEROXIDE (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII: W9WZ N9A0GM)	BENZOYL PEROXIDE	1 mg in 1 g		

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
LAURETH-4 (UNII: 6HQ855798J)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
WATER (UNII: 059QF0KO0R)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288-229- 10	1 in 1 PACKAGE	03/22/2019	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	03/22/2019	

# Labeler - Amazon.com Services LLC (128990418)

# Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		150931459	manufacture(72288-229)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Remar		938028602	repack(72288-229)

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